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MAGEC® MRI Compatibility

We are pleased to share that NuVasive® has been granted FDA clearance for use of Magnetic Resonance (MR) under certain conditions with the MAGEC system.

MAGEC is the only noninvasive solution for growth modulation in pediatric spinal deformity currently cleared by the FDA. The system's proprietary magnetic technology allows distraction of a growing rod construct in a clinical setting, helping reduce the number of surgeries required to treat patients with early onset scoliosis (EOS).

"Having clear, defined guidance for MRI compatibility with MAGEC helps alleviate uncertainty that may have limited surgeons from using the innovative MAGEC system," said Suken A. Shah, M.D., Division Chief of the Spine and Scoliosis Center and Clinical Fellowship Director at Nemours/Alfred I. duPont Hospital for Children. "This clearance opens up the door for more patients to benefit from this life changing technology."

The MR conditional clearance is one step toward integrating medical solutions and treatment options for the EOS population.

The MRI safety information is listed in the Instructions for Use and noted below.

MRI Safety Information:

Non-clinical testing demonstrated that the MAGEC System is MR Conditional. The following conditions must be followed:

A patient with this device can be scanned in an MR system meeting the following conditions:

- **Static magnetic field of 1.5 Tesla (1.5 T)**
- **Maximum spatial field gradient of 3000 gauss/cm (30 T/m)**
- **Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 0.5 W/kg at 1.5 T**

Under the scan conditions defined above, the MAGEC system is expected to produce a maximum temperature rise of no greater than 3.7° C after 15 minutes of continuous scanning. Additional considerations are listed on the following page.

MRI Safety Information Continued:

- Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength.
- The patient should not be permitted to roll on the table, as this motion may cause unintended lengthening/shortening of the implant.
- The External Remote Controller, Manual Distractor, and Wand Magnet Locator are MR Unsafe. Do not bring them into the MRI scan room.
- In non-clinical testing, the image artifact caused by the MAGEC® system extends beyond the imaging field of view when imaged with a gradient-echo pulse sequence in a 1.5 T MRI system. However, imaging in locations approximately 20cm away from the actuator of the MAGEC System may produce images in which anatomical features may be discerned.

If you have any further questions, please email magec@nuvasive.com or contact your local NuVasive® sales representative.